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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,295	02/05/2002	William H. Chapman JR.	021739-000120US	1026
20350	7590	05/04/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			COOK, LISA V	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/072,295

Applicant(s)

CHAPMAN ET AL.

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/22/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Applicants' election of Group I –claims 1-14, with traverse is acknowledged. (Paper filed 03 March 2004). Applicant does not traverse the Restriction Requirement because it lacks patentable distinctness. But objects on the ground(s) “that the examiner has not shown that a serious burden would be required to examine all of the claims” and all the claims arise out of a central concept or idea. This argument has been fully considered, but is not found convincing.

2. This is not found persuasive because MPEP § 808.02 recites:

Where related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c)- § 806.05(i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof, (B) A separate status in the art when they are classified together, or (C) A different field of search.

3. In the instant case, (A) -The Restriction Requirement under 35 U.S.C. § 121 in the paper number 01132004 established distinctness of the inventions and separate classification thereof:

4. (B) The inventions of Groups I, II, and III would require a separate status in the art when they are classified together; the invention as a whole is drawn to a separation reagent comprising compositions bound to micro particles. Such inventions are classified in 95, subclass 27 for example.

5. (C) With respect to a different field of search – Because these inventions are distinct and have acquired separate status in the art as shown by their different classification, recognized divergent subject matter and because the search required for each invention is not substantially coextensive with the search required for the remaining invention, restriction for examination purposes as indicated is proper. Please note that the classifications in the restriction are illustrative only and do **not** represent all the classes and subclasses, which must be searched for each invention; nor is the search limited to issued US patents, but rather includes published foreign patents and applications as well as literature search.

The Restriction Requirement is still deemed proper and is therefore made **FINAL**.

6. Currently, claims 1-26 are subject to Restriction and Election Requirement. Claims 15-26 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 1-14 are currently under examination.

#### ***Information Disclosure Statement***

7. The listing of references in the specification is not a proper information disclosure statement. For example see page 12. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner-on form PTO-892 or the applicant-on form PTO-1449 have cited the references they have not been considered.

8. The information disclosure statement (IDS) filed 22 May 2002 has been considered as to the merits before First Action.

9. The information disclosure statement filed 10/15/01 in paper #3 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language.

Translations for WO 96/31781, EP0408078A2, EP0332022A2, WO 96/31781, EP0408078B1, and EP0332022B1 were not received. They have been placed in the application file, but the information referred to therein has not been considered.

### *Specification*

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. The first page of the disclosure is not numbered. Please add "1".

II. The use of the trademarks has been noted in this application. (i.e. Dynal, Biomek, Beckman on page 2 and Pierce on page 6). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

***Claim Objections***

11. Claim 1 is objected to because of the following informalities: In claim 1 line 3 the recitation "and a receptor for a ligand on a target species in the biological sample" appears to be a typo. It is suggested that the claim read "and a receptor for a ligand to a target species in the biological sample" to obviate this objection. See MPEP 608.01(m).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is vague and indefinite because it is unclear in reciting "a method of processing a biological sample". Processing is a relative term which renders the claim indefinite. The term with regard to what "processing will entail" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Double Patenting***

**13. Double patenting obviousness-type rejection:**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9, 19, and 20 of copending Application No. 09/802,381. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The instant invention is encompassed within application number 09/802,381.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cervera et al. (Biochemistry, 1996, 35, 7247-7255) in view of Bangs Laboratory, Inc. (Tech Note #205, 8/31/99).

Cervera et al. disclose a method of employing UMP (receptor) a highly specific affinity-labeling reagent to bind lysine 992 (ligand) in carbamyl phosphate synthetase (CPS – target substance). The photo-affinity label <sup>14</sup>C-UMP is used to form an adduct via covalent binding between the target species ligand (lysine 992 of CPS) and the labeling receptor (<sup>14</sup>C-UMP). See abstract and page 7252 – Discussion. The UMP incorporated or bound to the CPS peptide is activated by UV irradiation (Claim 2). See page 7252 1<sup>st</sup> paragraph – lines 1-5.



The bound complex is subsequently separated and evaluated. See page 7252 1<sup>st</sup> column line 12 through 2<sup>nd</sup> column line 4. N-terminal sequencing proved important in locating the labeling region. See Table 2 on page 7252.

Cervera et al. differ from the instant invention in not specifically teaching a separation reagent providing the labeled receptor on a micro particles (micro sphere).

However, Bangs Laboratories (Tech Note #205) teach the use of micro particles having reagents covalently absorbed thereto. The micro particles are adsorbed to the reagents (i.e. ligands) by covalent attachment and include the coupling of chemical reactive groups (carboxyl, amino, hydroxyl, hydrazide, amide, chloromethyl, aldehyde, epoxy, tosyl). See page 1 of 10. The coupling protocols begin on page 4 of 10 and disclose the ability of the microparticle-ligand bound chemical reactive group to exhibit a signal in quenching solutions. Also see figures A – I.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the separation photo-affinity label receptor of Cervera et al. to a microparticle (micro sphere) as taught by Bangs Laboratories, Inc. because micro spheres or solid phase bound reagents in assay methods eliminate washing thereby reduce time and require less reagents.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the separation photo-affinity label receptor of Cervera et al. to a microparticle (micro sphere) as taught by Bangs Laboratories, Inc. because Bangs Labs teach that any ligand can be bound to micro spheres (page 1 of 10 – 2<sup>nd</sup> column).

Further, the combination of small molecules of interest can be problematic and these special difficulties can be overcome by combining carrier molecules and various type of cross linkers which extends the smaller molecules from the micro sphere surface, reducing steric hindrance, and increases activity. See page 9 of 10 – C.

II. Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cervera et al. (Biochemistry, 1996, 35, 7247-7255) in view of Bangs Laboratory, Inc. (Tech Note #205, 8/31/99) and in further view of Safarik et al. (Journal of Chromatography B, 722, 1999, pages 33-53).

Please see the discussion of Cervera et al. (Biochemistry, 1996, 35, 7247-7255) in view of Bangs Laboratory, Inc. (Tech Note #205, 8/31/99) as set forth above.

Cervera et al. (Biochemistry, 1996, 35, 7247-7255) in view of Bangs Laboratory, Inc. (Tech Note #205, 8/31/99) from the instant invention in not specifically teaching magnetic particle DNA isolation and detection in sperm cells.

However, Safarik et al. teach this limitation. Magnetic separation is taught to be combinable with conventional separation or identification processes to purify cells, cell organelles, and biologically active compounds (nucleic acids, proteins, xenobiotics).

See abstract. "Magnetic separation of cells has shown its self usefulness in many application where other procedures failed". Page 51 - 1<sup>st</sup> column. DNA methodologies are disclosed on page 50. The magnetic particle can be configured to include protein-binding materials such as antibodies. See page 42-44 Section 4.1.

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With respect to the sample being a forensic sperm cell, it is noted that Safarik et al. teach that the cell types can be conducted on any prokaryotic or eukaryotic cell. See page 42 section 4.1. Absent evidence to the contrary forensic sperm cells can be utilized as the sample for testing.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use magnetic particles in DNA analysis as taught by Safarik et al. in the assay by Cervera et al. (Biochemistry, 1996, 35, 7247-7255) in view of Bangs Laboratory, Inc. (Tech Note #205, 8/31/99) because Safarik et al. teach that their technique exhibits high specificity, can be easily scaled up, materials are readily available and inexpensive. Page 51 1<sup>st</sup> column 2<sup>nd</sup> paragraph.

One having ordinary skill in the art would have been motivated to do this because magnetic separation of cells has shown its usefulness in many applications where other procedures fail. The technique exhibits high specificity, can be easily scaled-up, many ready-to-use products are available and the basic equipment for standard work is relatively inexpensive. See page 51 section 7.

III. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cervera et al. (Biochemistry, 1996, 35, 7247-7255) in view of Bangs Laboratory, Inc. (Tech Note #205, 8/31/99)

Please see the discussion of Cervera et al. (Biochemistry, 1996, 35, 7247-7255) in view of Bangs Laboratory, Inc. (Tech Note #205, 8/31/99) as set forth above.

Cervera et al. (Biochemistry, 1996, 35, 7247-7255) in view of Bangs Laboratory, Inc. (Tech Note #205, 8/31/99) from the instant invention in not specifically teaching the diameter range of the micro particles employed.

However, Bangs Lab teach the importance of considering the diameter of the micro particles when coating with reagents. The reference gives a general formula  $S=(6/pD)(C)$  on page 2 of 10 as a means of achieving the surface saturation (optimization). Micro spheres or particles with a *mean* diameter of 1 micrometer are utilized in the reference. See page 2 of 10 2<sup>nd</sup> column for example.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use various sized or different diameter magnetic particles in the binding analysis' taught by Cervera et al. (Biochemistry, 1996, 35, 7247-7255) in view of Bangs Laboratory, Inc. (Tech Note #205, 8/31/99) because particles diameter variation was considered important in micro sphere coating these modification are routine optimizations that are almost always determined and used in particle immunoassay studies. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different sized/diameter micro particles in the given parameters to determine the unknown as a means of optimizing the assays provided by the art.

16. For reasons aforementioned, no claims are allowed.

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***Remarks***

17. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

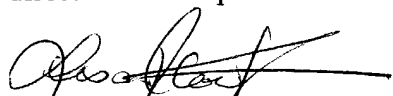
A. Sheabar et al. (Carcinogenesis, Vol.14, pages 1203-1208, 1993) disclose assays to quantitate aflatoxin-albumin adducts.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0818.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.



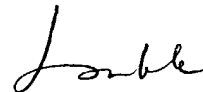
*Lisa V. Cook*

*Patent Examiner*

*Remsen 3C-59*

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*4/28/04*



**LONG V. LE  
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*04/30/04*